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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,047	04/14/2006	Katsuyuki Hamada	TSU-006	8849

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EXAMINER	
HILL, KEVIN KAI	

ART UNIT	PAPER NUMBER
1633	

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08/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,047	HAMADA ET AL.	
	Examiner	Art Unit	
	KEVIN K. HILL	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-9 and 11-25* is/are pending in the application.

4a) Of the above claim(s) *7-9,13,14 and 17-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-6,11,12,15,16 and 20-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *April 23, 2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Election/Restrictions

Applicant has elected the following species without traverse, wherein:

i) the virus is adenovirus, as recited in claim 2;

ii) the carrier cell is A549, as recited in claims 4 and 21-23;

iii) the promoter is 1A1.3B, as recited in claim 5;

iv) the therapeutic compound is atelocollagen, as recited in claim 6 and 16;

v) the viral administration rate of the virus for immunological treatment is set between about 10^5 viral particles and 10^{11} viral particles for a patient with antibody negative to the virus, as recited in claim 12.

Because Applicant did not distinctly and specifically point out the supposed errors in the Group or species restriction requirement, the election has been treated as an election without traverse and the restriction and election requirement is deemed proper and therefore made final (MPEP § 818).

Amendments

Applicant's response and amendments, filed February 18, 2008 and May 23, 2008, to the prior Office Action is acknowledged. Applicant has cancelled Claims 1 and 10, withdrawn Claims 7-9, 13-14 and 17-19, amended Claims 2-9 and 11-23, and added new claims, Claims 24-25. Applicant's new claims have been entered into the application as requested and will be examined on the merits herein, as they are considered to belong to the elected group.

Claims 7-9, 13-14 and 17-19 are pending but withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim.

Claims 2-6, 11-12, 15-16 and 20-25 are under consideration.

Priority

This application is a 371 of PCT/JP04/15220, filed October 15, 2003. A certified copy of PCT/JP04/15220, filed October 15, 2003, is filed with the instant application. Accordingly, the effective priority date of the instant application is granted as October 15, 2003.

Acknowledgment is made of Applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) of JP 2003-354983, filed October 15, 2003.

Response to Amendment

The Examiner has found the certified copy of JP 2003-354983 filed with the instant application in IFW (papers filed April 14, 2006). Accordingly, an updated Bib Data Sheet is provided with this Office Action.

Information Disclosure Statement

Applicant has filed an Information Disclosure Statement on April 23, 2008 that has been considered. The signed and initialed PTO Form 1449 is mailed with this action.

Examiner's Note

Unless otherwise indicated, previous objections/rejections that have been rendered moot in view of the amendment will not be reiterated. The arguments in the February 18, 2008 and May 23, 2008 responses will be addressed to the extent that they apply to current rejection(s).

Specification

1. **The prior objection to the disclosure is withdrawn** in light of Applicants amendments to the specification in the papers filed February 18, 2008, which is identical to the paper filed May 23, 2008 to correct the deficiencies regarding citation of the prior art, and the grammatical and idiomatic errors.

Claim Objections

2. **The prior objection to Claims 1, 3-4, 10 and 20-23 is withdrawn** in light of Applicant's amendment to the claims to spell out CTL, amend the dependency of claims 20-23.

3. **Claims 3-4 and 21-25 are objected to because of the following informalities**:

With respect to claims 24-25, the adjective "non-proliferative" (line 4) should be placed closer to its noun "virus" (line 2), as in "(a) a non-proliferative virus" so as to avoid any confusion about which entity—the virus or carrier cell—is required to be non-proliferative.

With respect to claims 3 and 20, the claims are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous

claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim recites that the virus for immunological treatment is selected from the group consisting of a non-proliferative virus and an inactivated virus. The specification discloses that a non-proliferative virus may be an inactivated virus (Amended Specification; pgs 17-18, joining ¶). Thus, the terms "non-proliferative" and "inactivated" are merely adjectives to describe the same virus.

With respect to claims 21 and 23, Applicant is advised that should claim 21 be found allowable, claim 23 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant case, the claims recite the same carrier cell type Markush group, wherein both claims are dependent on claim 2, and wherein claim 20 fails to further limit claim 2 (see above). Thus, claim 23 is the same scope and a duplicate of claim 21.

With respect to claims 4 and 22, Applicant is advised that should claim 4 be found allowable, claim 22 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). In the instant case, the claims recite the same carrier cell type Markush group, wherein both claims are dependent on claim 24, and wherein claim 3 fails to further limit the independent claim 24 (see above). Thus, claim 22 is the same scope and a duplicate of claim 4.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. **The prior rejection of Claims 1, 10-11 and 15-16 under 35 U.S.C. 112, second paragraph is withdrawn** in light of Applicant's amendments to the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. **Claim 12 is rejected under 35 U.S.C. 112 first paragraph**, because the specification as originally filed does not describe the invention as now claimed. Claim 12, amended on May 23, 2008, recites that the virus for immunological treatment is administered in an amount "to 0 viral particles to a patient who is positive for the antibodies to the virus". Clear support for the new limitation "0 viral particles" cannot be found in the instant application or priority documents. Accordingly, the amendment(s) to claim 12 is considered to constitute new matter.

> MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "WHENEVER THE ISSUE ARISES, THE FUNDAMENTAL FACTUAL INQUIRY IS WHETHER A CLAIM DEFINES AN INVENTION THAT IS CLEARLY CONVEYED TO THOSE SKILLED IN THE ART AT THE TIME THE APPLICATION WAS FILED...IF A CLAIM IS AMENDED TO INCLUDE SUBJECT MATTER, LIMITATIONS, OR TERMINOLOGY NOT PRESENT IN THE APPLICATION AS FILED, INVOLVING A DEPARTURE FROM, ADDITION TO, OR DELETION FROM THE DISCLOSURE OF THE APPLICATION AS FILED, THE EXAMINER SHOULD CONCLUDE THAT THE CLAIMED SUBJECT MATTER IS NOT DESCRIBED IN THAT APPLICATION". MPEP 2163.06 further notes "When an amendment is filed in reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. *Applicant should therefore specifically point out the support for any amendments made to the disclosure*" (emphasis added).

In the instant case, the specification as originally filed describes the lower limit of virus for immunological treatment to be 10^2 virus particles (Amended Specification, e.g. pg 4, ¶5 and pg 18, ¶2). The Examiner notes that the base claim requires the administration of a virus for immunological treatment (step (a)). Therefore, it logically follows that if 0 virus particles are administered to a patient who is positive for the antibodies to the virus, then the artisan has not performed the invention as required by the independent claim. Thus, the amendment is a

departure from or an addition to the disclosure of the application as filed, accordingly, it introduces new matter into the disclosure.

For reasons set forth above, the amendment filed May 23, 2008 is objected to under 35 U.S.C. §132 because it introduces new matter into the disclosure. 35 U.S.C. §132 states that no amendment shall introduce new matter into the disclosure of the invention. Applicant is required to cancel the new matter in the reply to this Office Action.

Alternatively, if Applicant believes that support for Claim 12, drawn to the virus for immunological treatment is administered in an amount "to 0 viral particles to a patient who is positive for the antibodies to the virus", is present in the instant application or earlier filed priority documents, Applicant must, in responding to this Office Action, point out with particularity, where such support may be found.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the Applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the Applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. **The prior rejection of Claims 1-3, 20 under 35 U.S.C. 102(b)** as being anticipated by Kikuchi et al (Blood 100:3950-3959, 2002; available online July 25, 2002) **is withdrawn** in light of Applicant's argument that Kikuchi et al fails to disclose a kit containing 3 ingredients: a virus for immunological treatment which is non- proliferative; a carrier cell which becomes infected with an oncolytic virus to produce an oncolytic virus infected carrier cell; and an oncolytic virus which is the same type of virus as the virus for immunological treatment and which is proliferative in the tumor cell, which the Examiner finds persuasive.

7. **Claims 2-3, 11-12, 15 and 20 stand, and claims 24-25 are newly, rejected under 35 U.S.C. 102(e)** as being anticipated by Terman, 2002/0177551 A1.

This rejection is maintained for reasons of record in the office action mailed October 16, 2007 and re-stated below. The rejection has been re-worded slightly based upon Applicant's amendment filed May 23, 2008.

With respect to claims 24 and 25, Terman discloses a cancer therapeutic drug and a method of treating tumors such as carcinoma, melanoma, sarcoma, leukemia and lymphoma (pg

8, [0055]), the method comprising a step of administering to a patient *in vivo* with a nucleic acid viral vector to induce a CTL reaction to a carrier cell expressing one or more desired antigens, e.g. a tumor antigen, and after a predetermined period of time, the method further comprising a step of administering to said patient carrier cells infected with an oncolytic virus (pg 54, [0544, 0549]; pg 90-91, [1057-1058, 1060, Example 7]), wherein said carrier cell may be a tumor cell (pg 8, [0052]).

With respect to claim 2, Terman discloses the virus may be an adenovirus (pg 10, [0075]; pg 11, [0082], [0086]).

With respect to claims 3 and 20, Terman discloses the virus may be replication-selective or inactivated (pg 55, [0556]; pg 161, [2087]).

With respect to claim 11, Terman discloses the predetermined period of time to be, for example, at least three weeks (pg 94, Table V).

With respect to claim 12, Terman discloses the use of 10^{10} virus particles (pg 159, [2067]).

With respect to claim 15, Terman discloses the carrier cell to be administered to the patient into the host tumor (pg 90, [1056]).

Response to Arguments

Applicant argues that:

a) Terman does not disclose a "virus for immunological treatment" or "administering a virus for immunological treatment to a patient". Rather, all viruses disclosed by Terman are used to transfect cells, rather than being directly administered to an animal or patient without first being used to transfect a cell.

b) a virus with SAg cannot be called an oncolytic virus since it does not infect the cancer cell in the body and cause the cancer cell to lyse.

Applicant's argument(s) has been fully considered, but is not persuasive.

With respect to a-b), Terman discloses that the virus for immunological treatment may be administered *in vivo*, without first being used to transfect a cell *in vitro* (e.g. pg 9, [0069-70]; pg 11, [0086]), wherein SAg stimulation is known to activate CD4+ and CD8+ T cells to recognize and lyse tumors specifically both *in vitro* and *in vivo* (pg 44, [0433]). Furthermore, it appears that Applicant has overlooked that Terman discloses the use of oncolytic viral vectors comprising SAg (pg 54, [0544]).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. **Claims 2-4, 11-12, 15 and 20-23 stand, and claims 24-25 are newly, rejected under 35 U.S.C. 103(a)** as being unpatentable over Terman (2002/0177551 A1) and Harrison et al (Human Gene Therapy 12(10): 1323-1332, 2001).

This rejection is maintained for reasons of record in the office action mailed October 16, 2007 and re-stated below. The rejection has been re-worded slightly based upon Applicant's amendment filed May 23, 2008.

Terman discloses a cancer therapeutic drug and a method of treating tumors such as carcinoma, melanoma, sarcoma, leukemia and lymphoma (pg 8, [0055]), the method comprising a step of administering to a patient *in vivo* with 10^{10} virus particles (pg 159, [2067]) comprising a nucleic acid viral vector to induce a CTL reaction to a carrier cell expressing one or more desired antigens, e.g. a tumor antigen, and after a predetermined period of time, e.g., at least three weeks (pg 94, Table V), the method further comprising a step of administering to said patient carrier cells infected with an oncolytic virus (pg 54, [0544, 0549]; pg 90-91, [1057-1058, 1060, Example V]), wherein said carrier cell may be a tumor cell (pg 8, [0052]), wherein the carrier cell is administered to the patient into the host tumor (pg 90, [1056]). Terman discloses the nucleic acid viral vector and oncolytic virus may be an adenovirus (pg 10, [0075]; pg 11, [0082], [0086]) and may be replication-selective or inactivated (pg 54, [0556]; pg 161, [2087]).

Terman does not disclose the carrier cell to be an A549 cell. However, at the time of the invention, Harrison et al taught the use of A549 cells to produce oncolytic adenoviruses in a method to treat tumors. Absent evidence to the contrary, nothing non-obvious is seen with substituting one tumor cell for another tumor cell because the simple substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Each tumor cell would be capable of allowing replication and production of replication-selective oncolytic viruses, for example.

Thus, the invention as a whole is *prima facie* obvious.

Response to Arguments

Applicant argues that Terman and Harrison et al do not disclose each and every feature of the independent claims 24-25.

Applicant's argument(s) has been fully considered, but is not persuasive. The response to Applicant's arguments regarding the disclosure of Terman (discussed above) is incorporated herein. Applicant does not contest the teachings of Harrison et al as applied to the substitution of one tumor cell for another tumor cell, specifically A539 cells, because the simple substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

9. **Claims 6 and 16 stand rejected under 35 U.S.C. 103(a)** as being unpatentable over Terman (2002/0177551 A1) and Harrison et al (Human Gene Therapy 12(10): 1323-1332, 2001), as applied to claims 2-4, 11-12, 15 and 20-25 above, and in further view of Ochiya et al (Curr. Gene Therapy 1: 31-52, 2001).

The prior cited art does not teach the kit or method to comprise atelocollagen. However, at the time of the invention, Ochiya et al reviewed the advantages of using atelocollagen to mediate controlled-release of bioactive agents of molecular medicines (pg 33, Figure 1). Ochiya et al teach that atelocollagen may be designed to degrade in vivo or be surgically removed (pg 38, Figure 5), is useful for the prolonged release of adenovirus vectors in vivo (pgs 40-41), and may be used as a carrier for cell-based therapies (pgs 46-47, Figure 12).

It would have been obvious to one of ordinary skill in the art to combine atelocollagen with the virus and cell as taught Terman with a reasonable chance of success because all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Thus, the invention as a whole is *prima facie* obvious.

Response to Arguments

Applicant argues that Terman, Harrison et al and Ochiya et al do not disclose each and every feature of the independent claims 24-25.

Applicant's argument(s) has been fully considered, but is not persuasive. The response to Applicant's arguments regarding the disclosure of Terman (discussed above) is incorporated herein. Applicant does not contest the teachings of Ochiya et al as applied to combining atelocollagen with the virus and cell as taught Terman with a reasonable chance of success

because all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

10. **Claim 5 stands rejected under 35 U.S.C. 103(a)** as being unpatentable over Terman (2002/0177551 A1), Harrison et al (Human Gene Therapy 12(10): 1323-1332, 2001) and Ochiya et al (Curr. Gene Therapy 1: 31-52, 2001), as applied to claims 2-4, 6, 11-12, 15-16 and 20-25 above, and in further view of Alemany et al (U.S. Patent 6,403,370 B1) and Barker et al (Genomics 38:215-222, 1996).

The prior cited art does not teach the oncolytic virus to comprise a 1A1.3B promoter. However, at the time of the invention, Alemany et al disclosed a method for killing tumor target cells, the method comprising an oncolytic adenoviral vector, wherein the oncolytic adenoviral vector comprises a tumor cell-activated promoter operably linked to the adenoviral E1 gene (col. 6, lines 24-37).

Alemany et al do not disclose the use of a 1A1.3B promoter. However, at the time of the invention, Barker et al taught that the identification of the promoter region for 1A1.3B and that 1A1.3B (also known as CA125) is an art-recognized ovarian cancer marker antigen.

It would have been obvious to one of ordinary skill in the art to substitute a tumor cell-activated promoter as taught by Terman for a 1A1.3B promoter as taught by Barker et al with a reasonable chance of success because the art recognized that products of the adenovirus E1 gene control the replication of the adenovirus vector in tumor cells, and thus the use of a tumor cell-activated promoter to regulate the expression of E1 gene products would confer or enhance specificity of viral replication in the tumor cells. The art also recognized the existence of many tumor-activated promoters, including 1A1.3B, wherein the 1A1.3B gene product is an art-recognized ovarian cancer marker antigen. Absent evidence to the contrary, nothing non-obvious is seen with substituting one tumor cell-activated promoter for another tumor cell-activated promoter because the simple substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. Each tumor cell-activated promoter would be capable of regulating the expression of E1 gene products so as to confer or enhance specificity of viral replication in the tumor cells..

Thus, the invention as a whole is *prima facie* obvious.

Response to Arguments

Applicant argues that Terman, Harrison et al, Ochiya et al, Alemany et al and Barker et al do not disclose each and every feature of the independent claims 24-25.

Applicant's argument(s) has been fully considered, but is not persuasive. The response to Applicant's arguments regarding the disclosure of Terman (discussed above) is incorporated herein. Applicant does not contest the teachings of Ochiya et al as applied to substituting a tumor

cell-activated promoter as taught by Terman for a 1A1.3B promoter as taught by Barker et al with a reasonable chance of success because the art recognized that products of the adenovirus E1 gene control the replication of the adenovirus vector in tumor cells, and thus the use of a tumor cell-activated promoter to regulate the expression of E1 gene products would confer or enhance specificity of viral replication in the tumor cells, and that nothing non-obvious is seen with substituting one tumor cell-activated promoter for another tumor cell-activated promoter because the simple substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. **Claims 2-6 and 20-24 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting** as being unpatentable over claims 1-5 of copending Application No. 10/575,894. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed cancer gene therapeutic drug in the co-pending application comprises the same structural elements as recited in the instant application, specifically an oncolytic adenovirus comprising a 1A1.3B promoter, an A549 carrier cell and atelocollagen.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Amendment

Applicants have indicated that they will deal with this rejection after the present claims are deemed otherwise allowable. However, it is noted that the provisional ODP rejections will be maintained until the aforementioned issues are resolved.

Conclusion

12. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Kevin K. Hill, Ph.D. whose telephone number is 571-272-8036. The Examiner can normally be reached on Monday through Friday, between 9:00am-6:00pm EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Joseph T. Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin K. Hill, Ph.D./
Examiner, Art Unit 1633

/Q. JANICE LI, M.D./
Primary Examiner, Art Unit 1633